

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

JOHNSON & JOHNSON, a New
Jersey corporation; JANSSEN
BIOTECH, INC., a Pennsylvania
corporation,

Plaintiffs,

v.

SAMSUNG BIOEPIS CO. LTD., a
Korean corporation,

Defendant.

Civil Action No. 3:25-cv-01439

Hon. Georgette Castner, U.S.D.J.

Hon. Justin T. Quinn, U.S.M.J.

**DEFENDANT SAMSUNG BIOEPIS, LTD'S BRIEF IN SUPPORT OF
MOTION TO REDACT AND SEAL CERTAIN DOCUMENTS RELATING
TO PLAINTIFFS' PRELIMINARY INJUNCTION MOTION AND
ALTERNATIVE SERVICE MOTION, AND DEFENDANT'S ANSWER**

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INTRODUCTION

Pursuant to Local Civil Rule 5.3, Defendant Samsung Bioepis Co. Ltd. (“Samsung”) respectfully files this motion to seal and redact portions of the following under-seal docket entries, which relate to Plaintiffs Johnson & Johnson and Janssen Biotech, Inc.’s (together, “Janssen”) Motion for an Order to Show Cause for Alternative Service (Dkt. No. 9, the “Alternative Service Motion”), Janssen’s Motion for an Order to Show Cause for Preliminary Injunction (Dkt. No. 8, the “PI Motion”), Samsung’s Opposition to Plaintiffs’ Motion for Entry of a Preliminary Injunction (Dkt. No. 19, the “PI Opposition”), and Samsung’s Answer, Counterclaim, and Certification Pursuant to Local Civil Rule 11.2 (Dkt. No. 66, the “Answer”): (i) Exhibits 10 and 14 to the Declaration of Nathan Monroe-Yavneh in Support of the PI Motion (Dkt. Nos. 8-2 and 8-3, the “Monroe-Yavneh Declaration”); (ii) Exhibits 5 and 6 to the Declaration of Sunghun Son in Support of the PI Opposition (Dkt. No. 19-5, the “Son Declaration”); (iii) Exhibits 1-3 to the Declaration of Byoungin Jung in Support of the PI Opposition (Dkt. No. 19-1, the “Jung Declaration”); (iv) Paragraph 10 of the Declaration of Kris Soyoung Lee in Support of the PI Opposition (Dkt. No. 19-2, the “Lee Declaration”); (v) Exhibit 1 to the Monroe-Yavneh Declaration; (vi) Exhibit A to the Declaration of Jeffrey J. Greenbaum in Support of the Alternative Service Motion (Dkt. Nos. 9-1 and 9-2, the “Greenbaum Declaration”); and (vii) Exhibits A and B to the Answer.

Each of these materials contains confidential commercial, and/or proprietary information, the public disclosure of which would result in harm to Samsung and Samsung's nonparty business partners, as described in greater detail below and in the supporting declaration of Sunghun Son attached hereto ("Son Sealing Declaration"). Accordingly, Samsung now moves to permanently seal them.

BACKGROUND

On February 24, 2025, Janssen filed the PI Motion, asking the Court to issue a preliminary injunction preventing Samsung from launching its ustekinumab-ttwe product ("SB17"), a biosimilar to Janssen's STELARA[®], under the private label of its commercialization partner, Quallent Pharmaceuticals Health, LLC ("Quallent"). That same day, Janssen also filed the Alternative Service Motion, seeking permission to use alternative service to serve Samsung with process; the motion was granted on February 26, 2025, *see* Dkt. No. 11. Samsung filed the PI Opposition on March 6, 2025, and Janssen filed a reply on March 10, 2025. After oral argument, the Court denied Janssen's PI Motion due to Janssen's inability to establish a likelihood of irreparable harm warranting extraordinary relief. *See* Dkt. No. 61 ("Opinion"). All of the preliminary injunction briefing and materials filed in support thereof were temporarily filed under seal.

On May 12, 2025, Samsung filed its Answer, responding to the allegations in the Complaint and asserting a declaratory judgment counterclaim.

The parties submitted a number of documents containing sensitive commercial information of Samsung and its business partners in support of the PI Motion, the PI Opposition, and the Answer. The following materials (collectively, the “Samsung Confidential Materials”) are the subject of this motion: (i) Exhibits 10 and 14 to the Monroe-Yavneh Declaration (the “Sublicenses”), which are full copies of licensing agreements between Samsung and its commercialization partners Sandoz AG (“Sandoz”) and Quallent; (ii) Exhibit 5 to the Son Declaration and Exhibit A to the Answer, which are both full copies of a commercialization agreement between Samsung and Sandoz (the “Sandoz Agreement”); (iii) Exhibit 6 to the Son Declaration and Exhibit B to the Answer (the “PLD Agreement”), which are both full copies of a private label distribution agreement among Samsung, Sandoz, and Quallent; (iv) Exhibits 1-3 to the Jung Declaration, which are materials submitted to the FDA in connection with Samsung’s BLA application for SB17; and (v) Paragraph 10 of the Lee Declaration, which specifies the cost and time of Samsung’s development of SB17. In addition, in support of the Alternative Service Motion and the PI Motion, Plaintiffs filed Exhibit 1 to the Monroe-Yavneh Declaration and Exhibit A to the Greenbaum Declaration, which are both copies of the Settlement and License Agreement between Janssen and Samsung (the “Settlement Agreement” and collectively with the Samsung Confidential Materials, the “Confidential

Materials”). The Settlement Agreement contains sensitive commercial information of both Janssen and Samsung.

LEGAL STANDARD

While there is a presumptive right of public access to filed material, sealing is authorized where “the material is the kind of information that courts will protect and . . . disclosure will work a clearly defined and serious injury to the party seeking closure.” *In re Avandida Mktg., Sales Practices & Products Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019). Local Civil Rule 5.3 permits a party to file materials containing confidential information under seal and to file a motion to seal that information, provided the motion to seal describes the following: (a) the nature of the materials or proceedings at issue; (b) the legitimate private or public interest which warrant the relief sought; (c) the clearly defined and serious injury that would result if the relief sought is not granted; (d) why a less restrictive alternative to the relief sought is not available; (e) any prior order sealing the same materials in the pending action; and (f) the identity of any party or nonparty known to be objecting to the sealing request.

ARGUMENT

The Confidential Materials warrant sealing because (1) they contain Samsung’s potential trade secrets and proprietary business information, the disclosure of which would injure the parties’ abilities to compete in the market, (2)

Samsung’s interest in protecting this information outweighs the public interest in disclosure, and (3) there is no less restrictive alternative to the sealing and/or redactions sought.

A. The Confidential Materials Contain Sensitive, Proprietary Business Information

The Confidential Materials contain sensitive proprietary information of Samsung, as well as Samsung’s third-party business partners. Specifically, as set forth in detail in the attached Son Sealing Declaration, the Confidential Materials contain: information about the formulation and characteristics of Samsung’s SB17 Product; information about the development process for Samsung’s SB17 Product; information about Samsung and its nonparty partners’ business strategies for commercializing SB17; detailed commercial terms in Samsung’s agreements with these same nonparty partners and in the Settlement Agreement between Samsung and Janssen. *See* Son Sealing Decl., Ex. A.

It is well established that “[d]ocuments containing trade secrets or other confidential business information may be protected from public disclosure.” *Leucadia, Inc. v. Applied Extrusion Techs., Inc.*, 998 F.2d 157, 166 (3d Cir. 1993); *see also Smarte Carte Inc. v. Innovative Vending Sols., LLC*, 2024 WL 4025021, at *2 (D.N.J. July 12, 2024) (“the inclusion of trade secrets and other confidential information in documents warrants the sealing of such documents.”). Courts do not “permit their files to serve as . . . sources of business information that might harm a

litigant's competitive standing.” *Leucadia*, 998 F.2d at 166. Accordingly, “[t]he presence of trade secrets or other confidential information weighs against public access and . . . documents containing such information may be protected from disclosure.” *In re Gabapentin Patent Lit.*, 312 F. Supp. 2d 653, 664 (D.N.J. 2004); *see also Nixon v. Warner Commc'ns, Inc.*, 435 U.S. 589, 598 (1978) (recognizing the “common-law right of inspection has bowed before the power of a court to insure its records are not . . . [a] source[] of business information that might harm a litigant's competitive standing”) (citations omitted).

Maintaining the Confidential Materials under seal as requested herein is justified and necessary because disclosure of the sensitive proprietary information contained therein could “result in a clearly defined and serious injury” to both Samsung and its nonparty business partners. *In re Gabapentin Patent Lit.*, 312 F. Supp. 2d at 664; *see Son Sealing Decl.*, Ex. A. In particular, disclosure of Samsung's Sublicenses to Sandoz and Quallent (Dkt. No. 8-3, Exs. 10, 14) or of the Settlement Agreement would result in competitors of both Samsung and its partners “hav[ing] access to sensitive information that could be used against them in the marketplace.” *Bright v. Asset Acceptance, LLC*, 292 F.R.D. 190, 203 (D.N.J. 2013) (granting motion to seal of a master service agreement between defendant and a non-party). Such information would give an unfair competitive advantage to Samsung's, Quallent's, and Sandoz's—competitors, as well as to any future potential business

partners with which Samsung, Qualient, or Sandoz may negotiate. *See Vista India, Inc. v. Raaga, LLC*, 2008 WL 834399, at *4 (D.N.J. Mar. 27, 2008) (“If [defendant’s] competitors become aware of the terms in the agreements, they can successfully prevent [defendant] from obtaining future license agreements with their current or future licensors. In addition, disclosure would give future potential customers an advantage in negotiation if they are able to view [defendant’s] past and current agreements. This is a sufficient harm to seal the documents.”).

The same is true of disclosure of Samsung’s commercial agreements with Sandoz and Qualient, the Sandoz Agreement (Dkt. No. 19-5, Ex. 5; Dkt. No. 66, Ex. A) and the PLD Agreement (Dkt. No. 19-5, Ex. 6; Dkt. No. 66, Ex. B). *See* Son Sealing Decl., Ex. A. In addition to negotiated terms, these agreements reveal detailed information about Samsung, Sandoz, and Qualient’s strategies for commercializing SB17—the disclosure of which could cause all three “substantive competitive harm if disclosed to the public and to competitors.” *See Piramal Healthcare UK, Ltd. v. Novartis AG*, 2019 WL 11307647, at *2 (D.N.J. Oct. 10, 2019) (granting motion to seal where the documents at issue “contain[ed] highly confidential commercial information, as well as sensitive, proprietary business information . . . and which could cause [plaintiff] and a non-party to this litigation substantive competitive harm if disclosed to the public and to competitors.”).

Finally, Samsung’s FDA submission materials for SB17 (Dkt. No. 19-1, Jung Decl., Ex. 1-3) and Paragraph 10 of the Lee Declaration (Dkt. No. 19-2) contain proprietary—and in some cases trade secret—information about the formulation and development of Samsung’s SB17 product. *See* Son Sealing Decl., Ex. A. Such “product formulation development, ingredients, and other private confidential business information” “would be compromised and expose [Samsung] to substantial financial risk and serious injury should they become publicly available.” *Supernus Pharms., Inc. v. TWi Pharms., Inc.*, 2017 WL 11634614, at *3 (D.N.J. Aug. 28, 2017).

B. Samsung’s Interest in Protecting its Confidential Business Information Outweighs Any Potential Public Interest in the Confidential Materials

Any countervailing public interest is outweighed by Samsung’s interest in protecting its confidential information and the confidential information of its business partners from disclosure to competitors. The materials that Samsung seeks to seal are not “important to public health and safety” and would not substantially “promote fairness and efficiency” through “the sharing of information among litigants.” *LEAP Systems, Inc. v. MoneyTrax, Inc.*, 638 F.3d 216, 222 (3d Cir. 2011). The Confidential Materials are commercial contracts negotiated between private parties, which “demonstrate a clear intent to maintain confidentiality” in light of their confidentiality provisions, *id.* at 222-23, and proprietary information regarding

Samsung's SB17 product. All of this information relates to the business of a private party—as well as the businesses of two private nonparties, Sandoz and Quallent—none of which is a matter of significant importance to the public at large. *Cf. Overton v. Sanofi-Aventis U.S., LLC*, 2014 WL 1554718, at *2 (D.N.J. Apr. 9, 2014) (granting motion to seal where “the factors weighing against the interest of privacy, such as public safety, greater fairness, and efficiency, [were] not present”).

C. Samsung's Request Seeks to Protect the Confidential Materials by the Least Restrictive Means Necessary

Through this motion, Samsung seeks to maintain under seal a limited set of materials filed in support of the PI Motion, PI Opposition, Alternative Services Motion, and Answer. Rather than seeking to seal all materials related to these filings, Samsung seeks to seal only those materials subject to confidentiality terms or containing highly sensitive business information that could cause harm to Samsung (or Quallent or Sandoz) if disclosed to its competitors and others in the pharmaceutical industry.

In addition to seeking to seal only a limited set of materials, Samsung's requests as to each of the Confidential Materials are as narrow as possible. With respect to the various contracts sought to be sealed—including the Settlement Agreement, the Sublicenses, the Sandoz Agreement, and the PLD Agreement—Samsung does not object to the public disclosure of any particular provisions referenced in the preliminary injunction briefing, hearing transcript, or the Court's

order (Dkt. Nos. 8, 19, 23, 60, and 61)—*i.e.* the provisions that are pertinent to the parties’ arguments and the Court’s decision on the issues. Sealing only the underlying agreements—the vast majority of which were not implicated at all by the parties’ arguments or the Court’s decision—will have no impact on the public’s ability to understand the issues before the Court or the Court’s reasoning. Similarly, with respect to the Exhibits 1-3 of the Jung Declaration, there is no less restrictive alternative to protect such information available than sealing such documents in full. The documents contain highly confidential and trade secret information about the development of Samsung’s proprietary drug, and their contents were not quoted in any of the parties’ substantive briefing, the hearing transcript, or the Court’s opinion. Finally, with respect to Paragraph 10 of the Lee Declaration, Samsung seeks only to redact Paragraph 10 rather than seal the declaration in full, limiting its request to the least restrictive means possible of protecting the information therein.

CONCLUSION

For the foregoing reasons, Samsung respectfully requests that the Court grant its motion to seal the specified materials filed in support of the Alternative Service Motion, PI Motion, PI Opposition, and Answer.

Respectfully submitted,

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